

Working Together to Reduce Infant Sleep-Related Deaths:

WHAT YOU NEED TO KNOW NOW

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Disclosures

I have documented that I have no financial relationships to disclose or Conflicts of Interest (COIs) to resolve.

I have documented that my presentation will not involve discussion of unapproved or off-label, experimental use of a product, drug or device

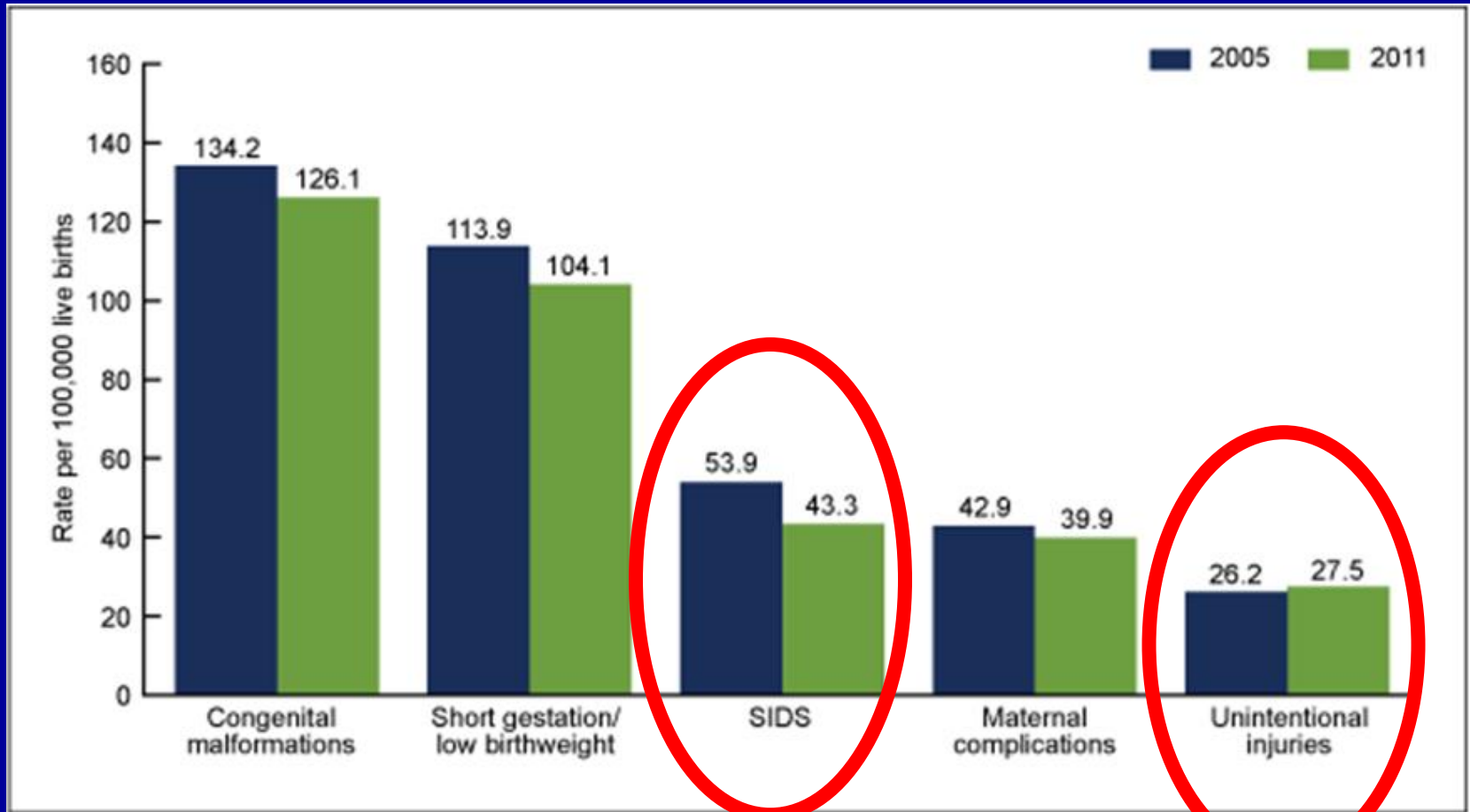


Objectives for Today's Talk

- Definition of SUID and SIDS
- Statistics on SIDS and accidental sleep deaths
- Pathophysiology of SIDS
- 2016 AAP recommendations: SIDS risk reduction and suffocation prevention



Infant mortality rates for the five leading causes of infant death in United States, 2005 and 2011

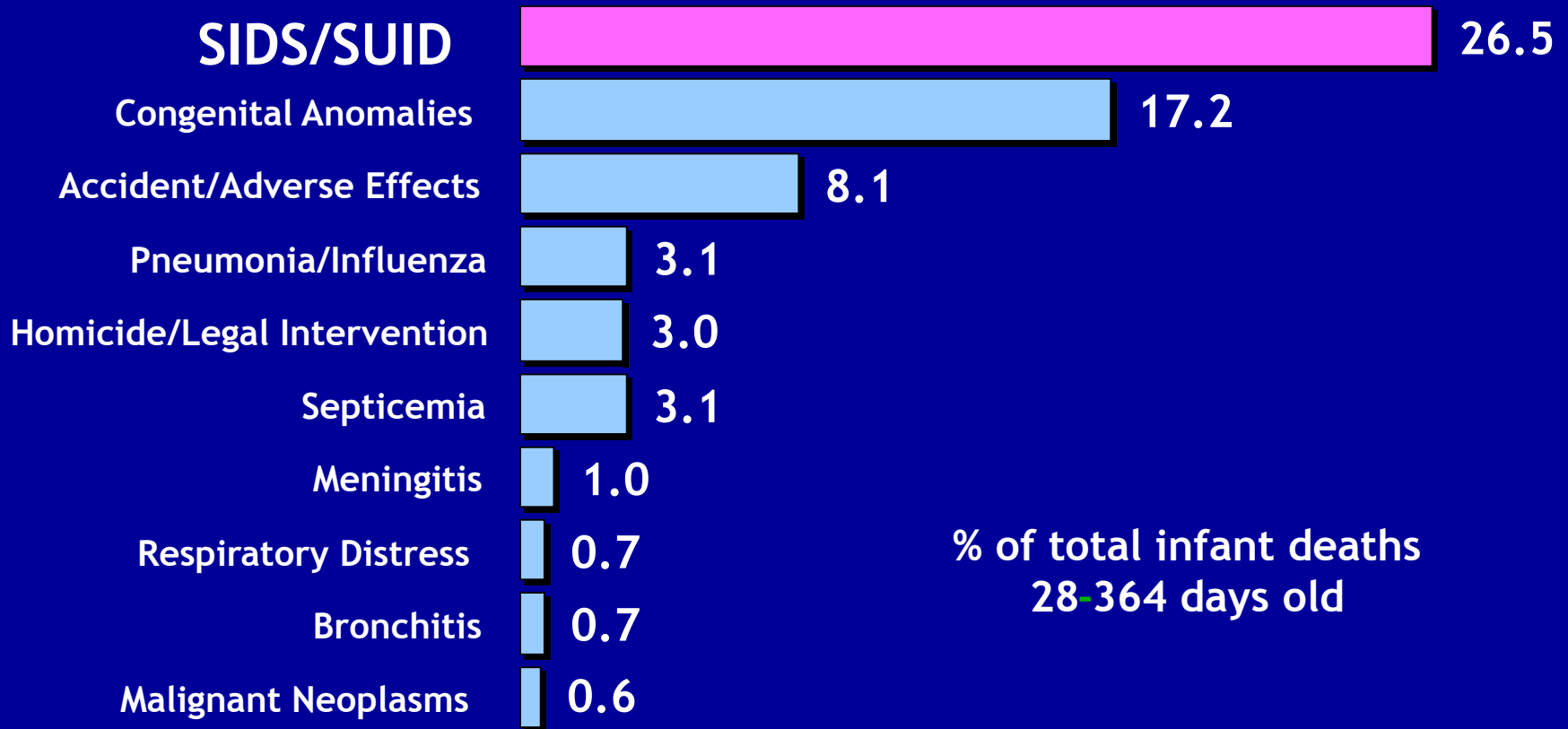


24,000 deaths per year

Infant Mortality Statistics

SIDS/SUID - United States 1999

The major cause of infant death after the first month

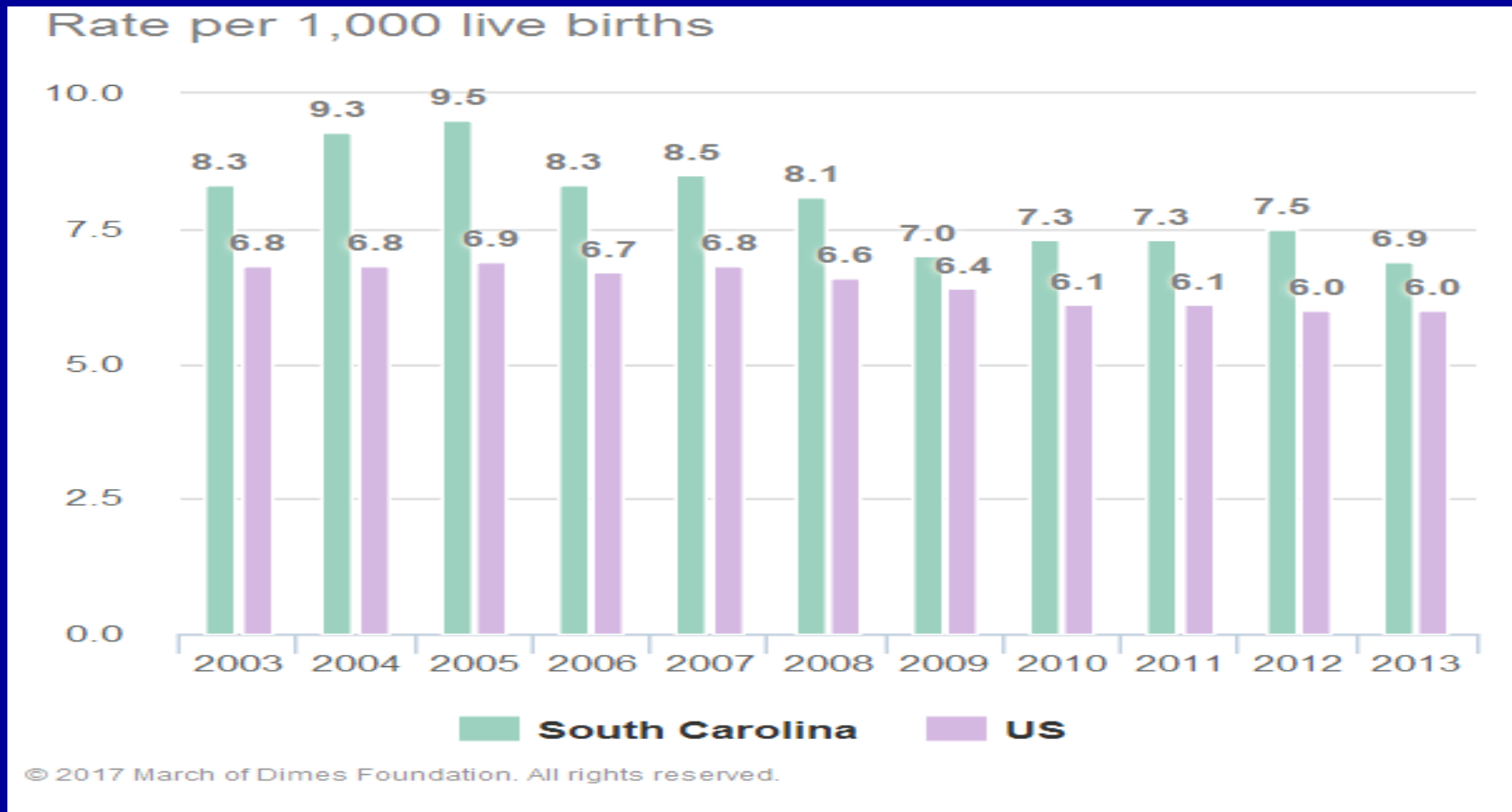


FACT:

3700 babies in the US die suddenly
and unexpectedly each year!



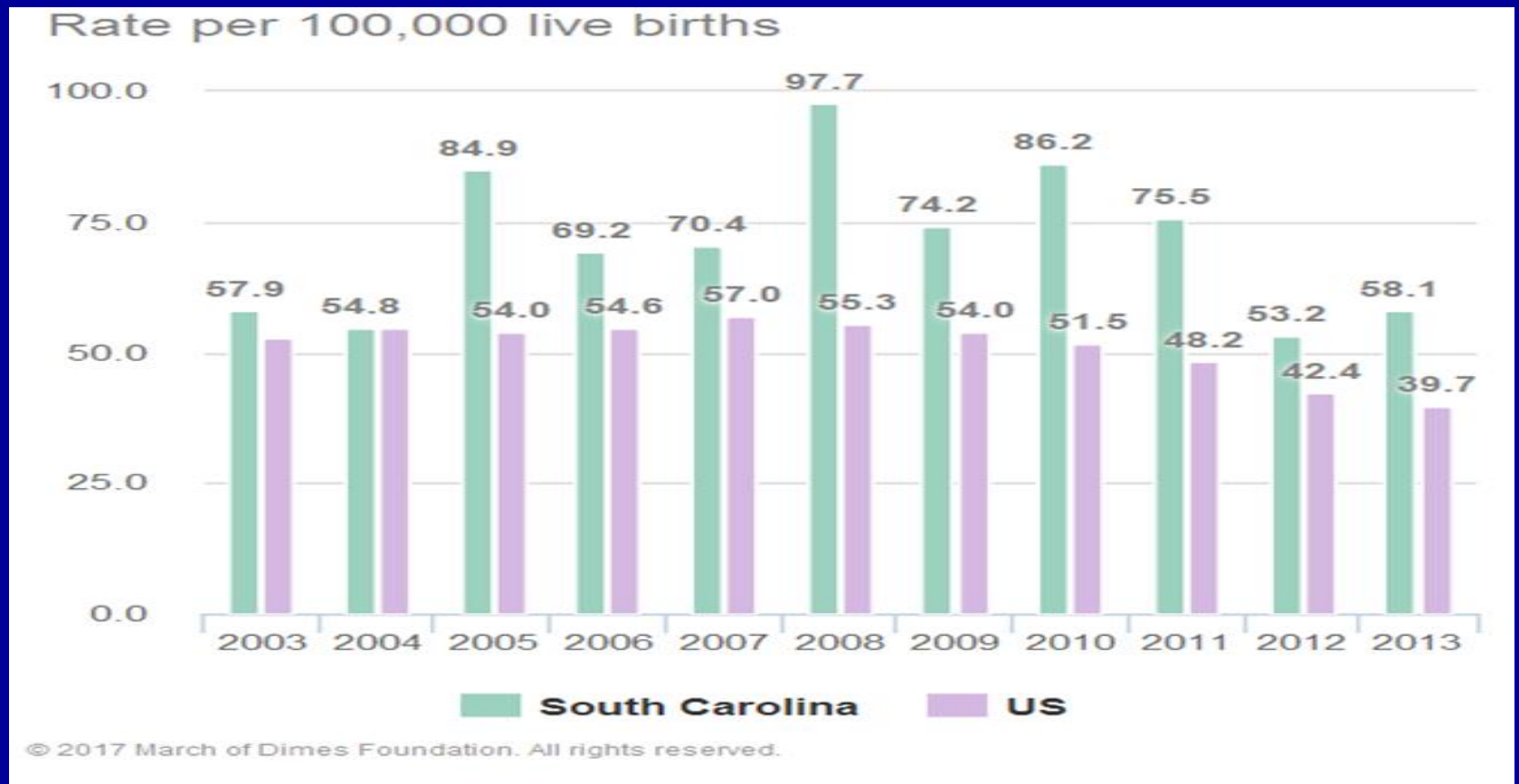
SC vs. US IMR 2002-2013



An infant death occurs within the first year of life.

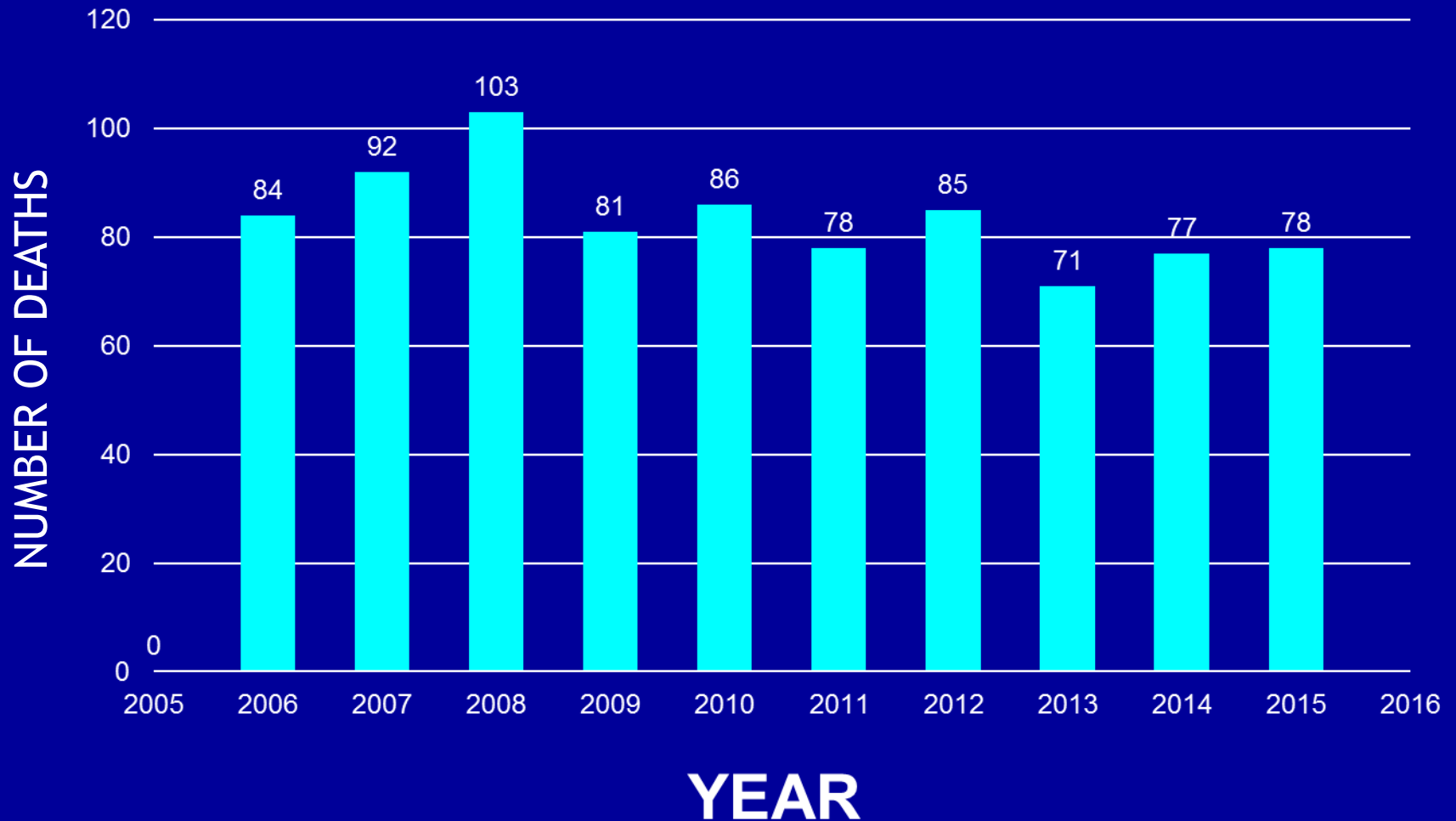
Source: National Center for Health Statistics, final mortality data, 1990-1994 and period linked birth/infant death data, 1995-present. Retrieved November 10, 2017, from www.marchofdimes.org/peristats

SC vs. US SIDS 2002-2013

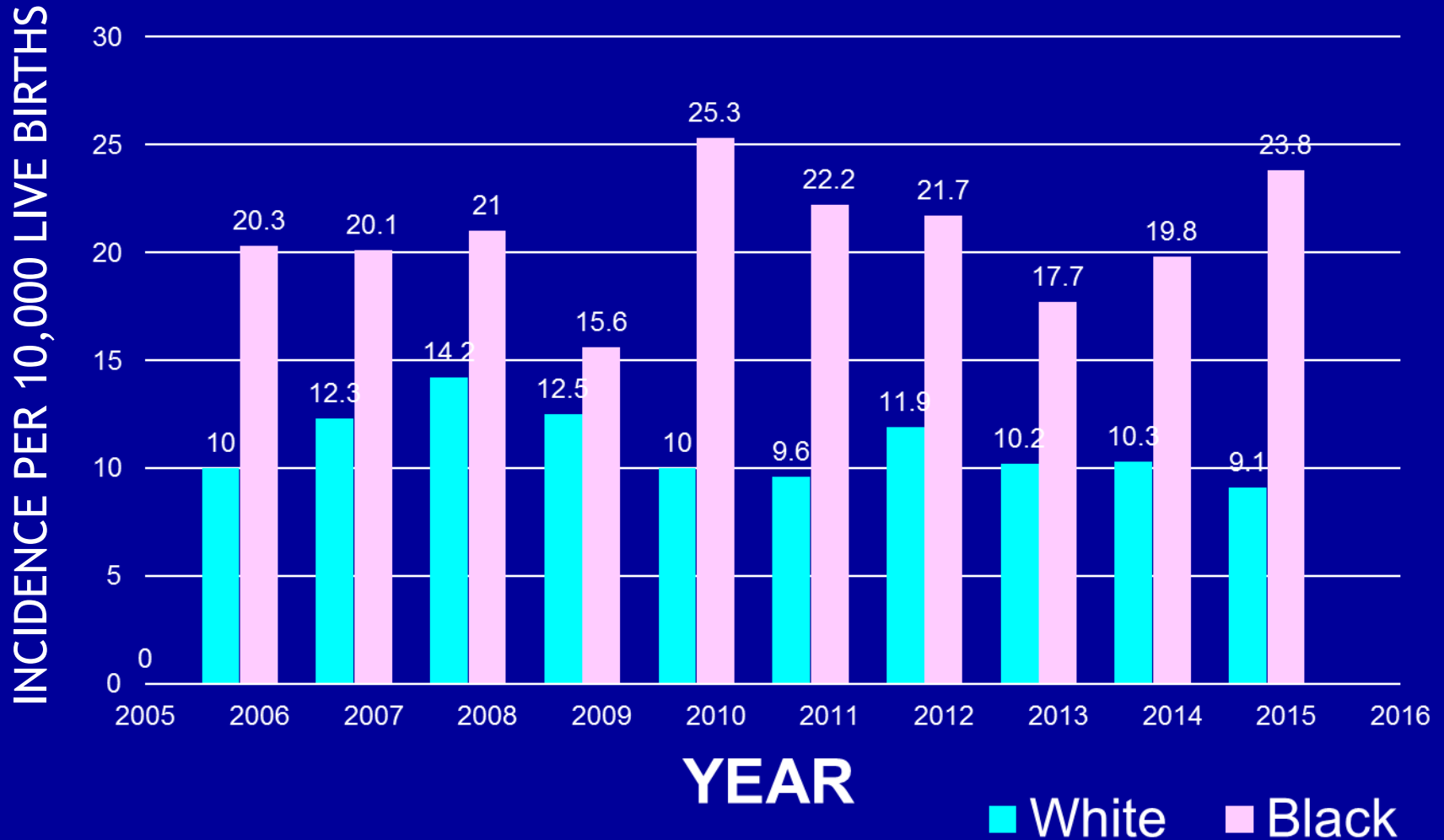


Cause of death for 1996-1998 is based on the Ninth Revision, International Classification of Diseases (ICD-9); cause of death for after 1998 is based on the Tenth Revision, International Classification of Diseases (ICD-10). Source: National Center for Health Statistics, period linked birth/infant death data. Retrieved November 10, 2017, from www.marchofdimes.org/peristats.

SC SUID 2006-2015



SC SUID INCIDENCE 2006-2015



SUID in SC 2009-2015

Table 7. Breakdown of Sudden Unexplained Infant Deaths

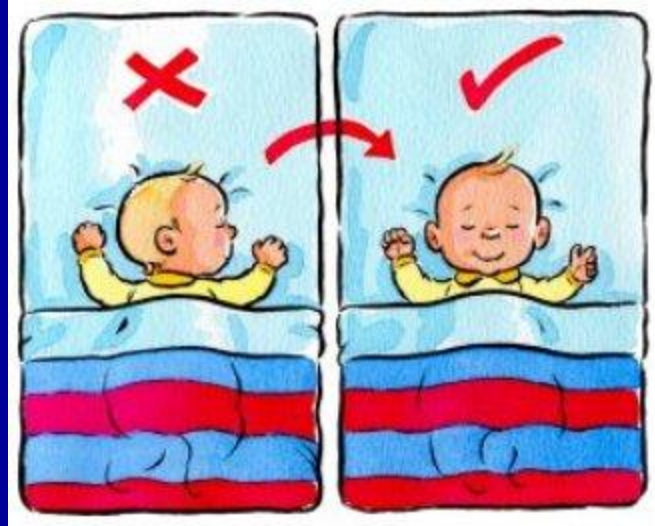
	2009	2010	2011	2012	2013	2014	2015	Total (2009-2015)
Accidental suffocation and strangulation in bed (W75, W84)	22	25	21	39	21	31	35	194
Sudden Infant Death Syndrome (R95)	44	49	45	33	35	31	28	265
Hanging, strangulation, and suffocation, undetermined intent (Y20)	5	4	2	1	9	4	4	29
Other ill-defined and unspecified causes of mortality (R99)	8	8	10	12	6	11	11	66
Total	79	86	78	85	71	77	78	554

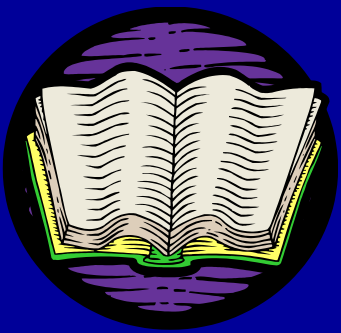
SUID in SC

- Infants placed on adult beds (bed sharing)
- Babies placed on pillows or pillow like devices
- Some infants placed in an unsafe position or had objects in sleep area
- None were found to be in a safe sleep environment
- Safe sleep environments available in the home
 - Majority of the cribs, bassinets, portable cribs were utilized for storage of items (clothes, diapers, wipes, toys etc...)

Infant Sleep Safety

- Requires a consistent and repetitive message in the community to prevent accidental deaths





Definitions

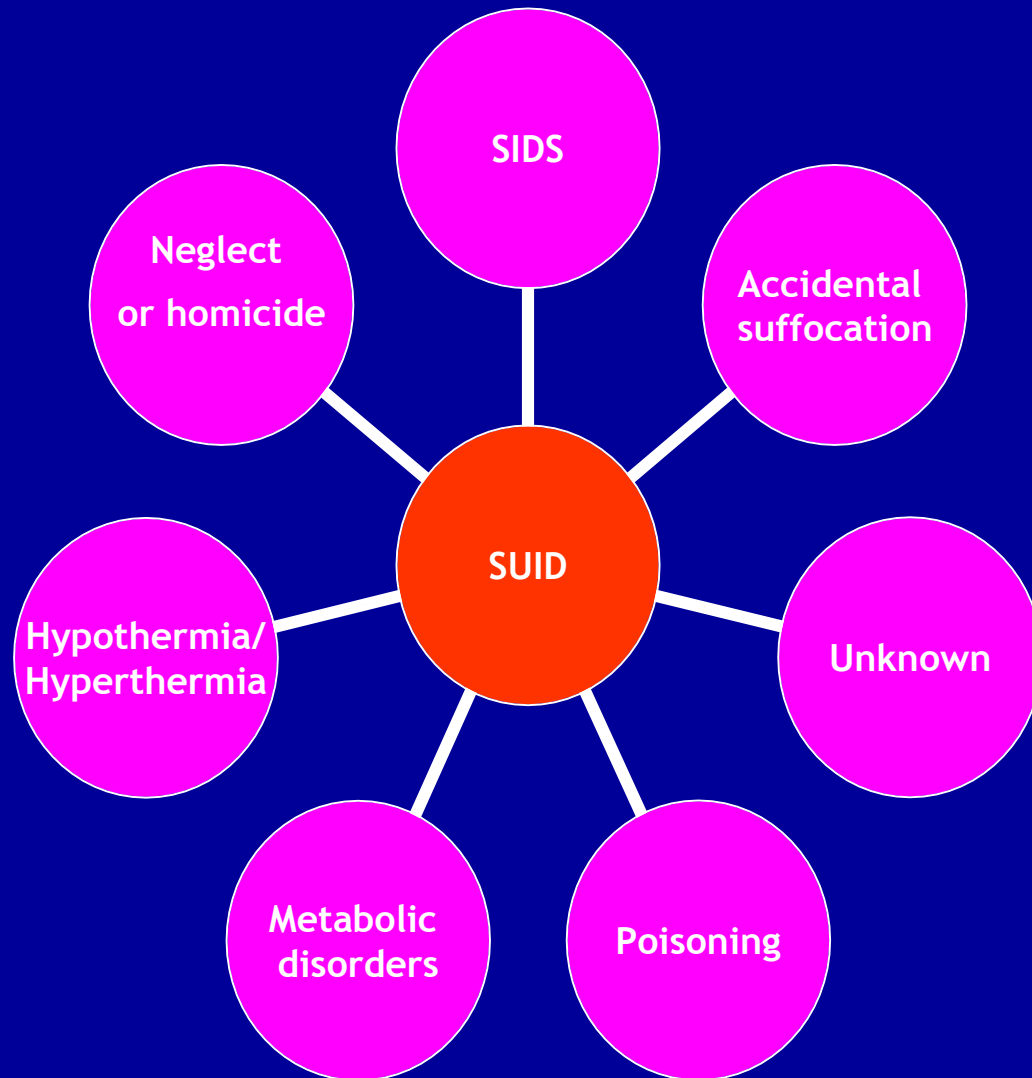
- Co-sleeping: a vague and confusing term to describe shared sleeping arrangements between infant and parents
- Bedsharing: any individual sharing a sleeping surface with an infant
- Roomsharing: parent and infant sleep proximate in the same room, on separate sleep surfaces



What is SUID or SUDI?

- Sudden Unexpected Infant Death
 - Occurs in a previously healthy infant
 - Can be explained or unexplained
 - Explained: trauma, drowning, suffocation
 - Unexplained: SIDS, undetermined
 - Most unobserved, during sleep/environment
- Sleep-related deaths
- SIDS represents a subcategory of SUID

Some causes of deaths that occur suddenly and unexpectedly during infancy



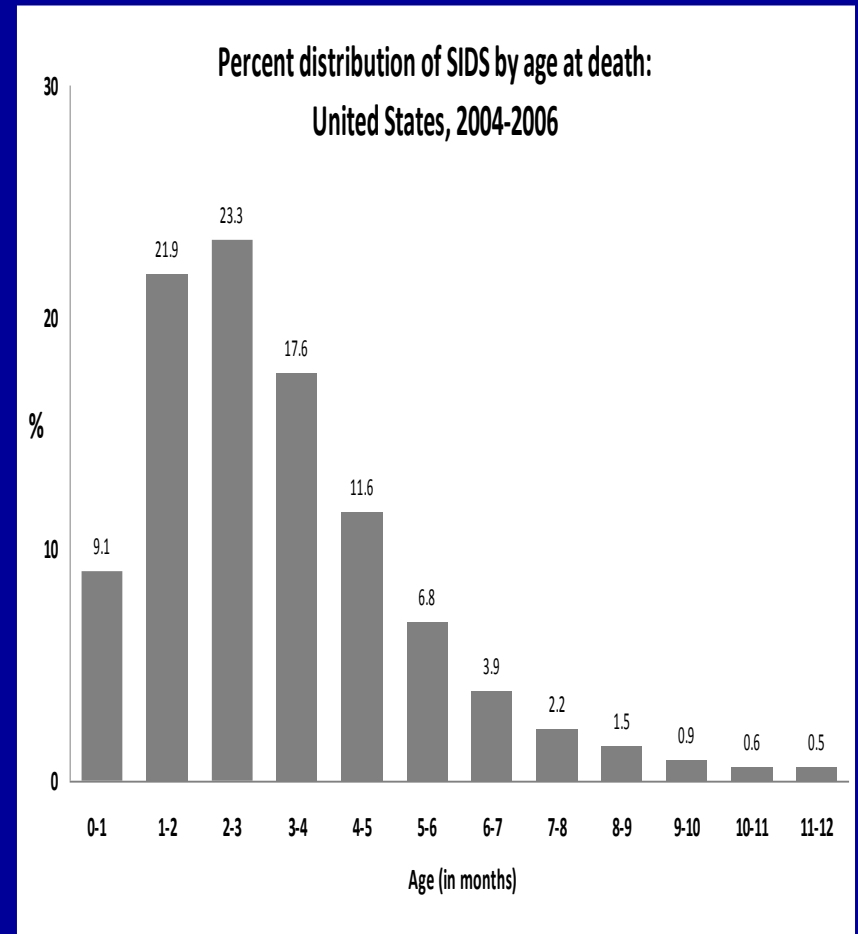
What is SIDS?

ICD-10 Definition: The sudden death of an infant under one year of age which remains unexplained after the performance of a complete post-mortem investigation including:

- Performance of a complete autopsy
- Examination of the death scene
- Review of the case history

SIDS FACTS

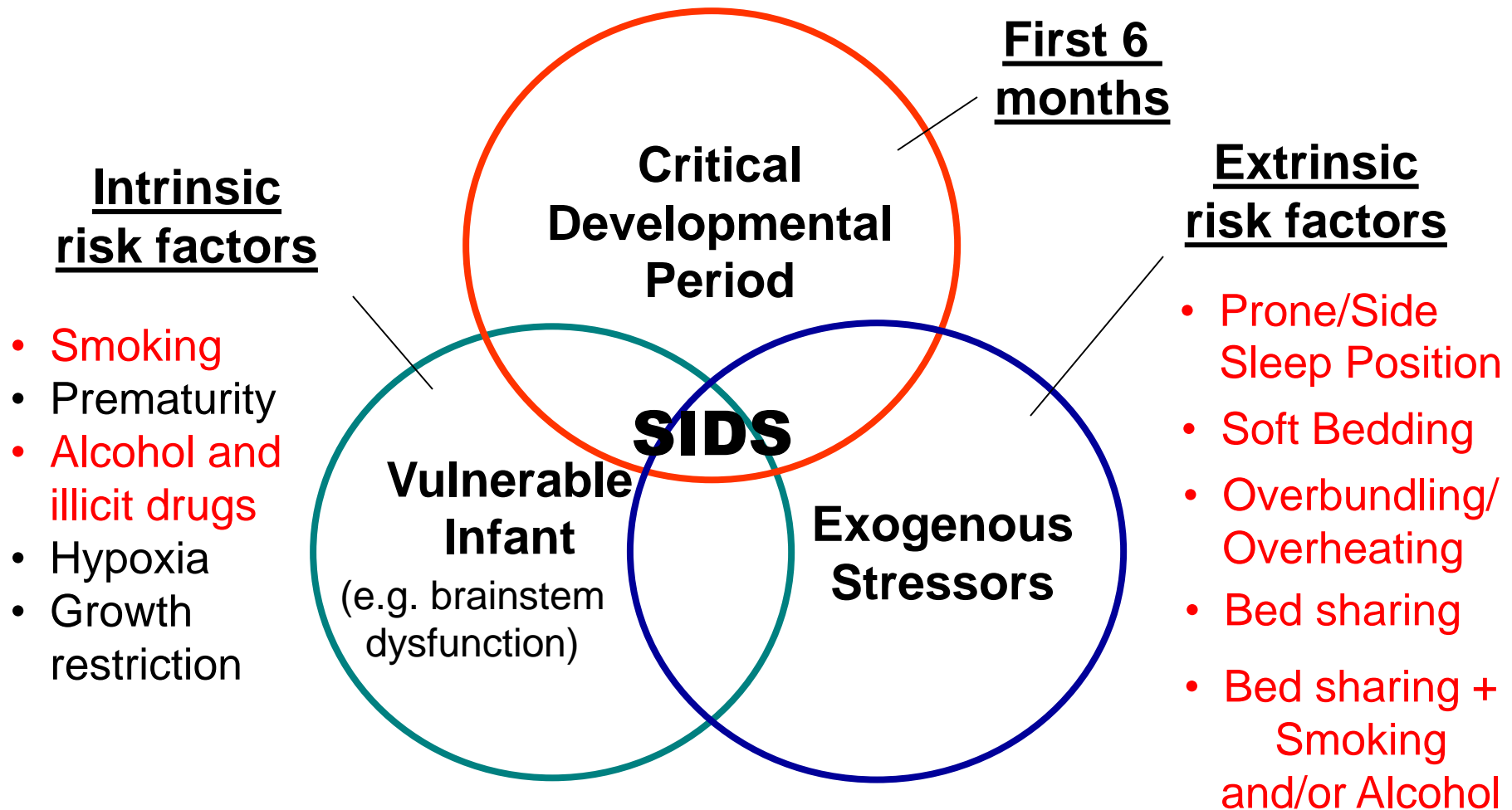
- The leading cause of death in infants from one month to one year of age (post-neonatal infant mortality)
- A diagnosis of exclusion. The cause of death is assigned only after ruling out other causes
- Peak time of occurrence: 1-4 months
- Higher incidence in males
- No longer see a higher frequency in colder months



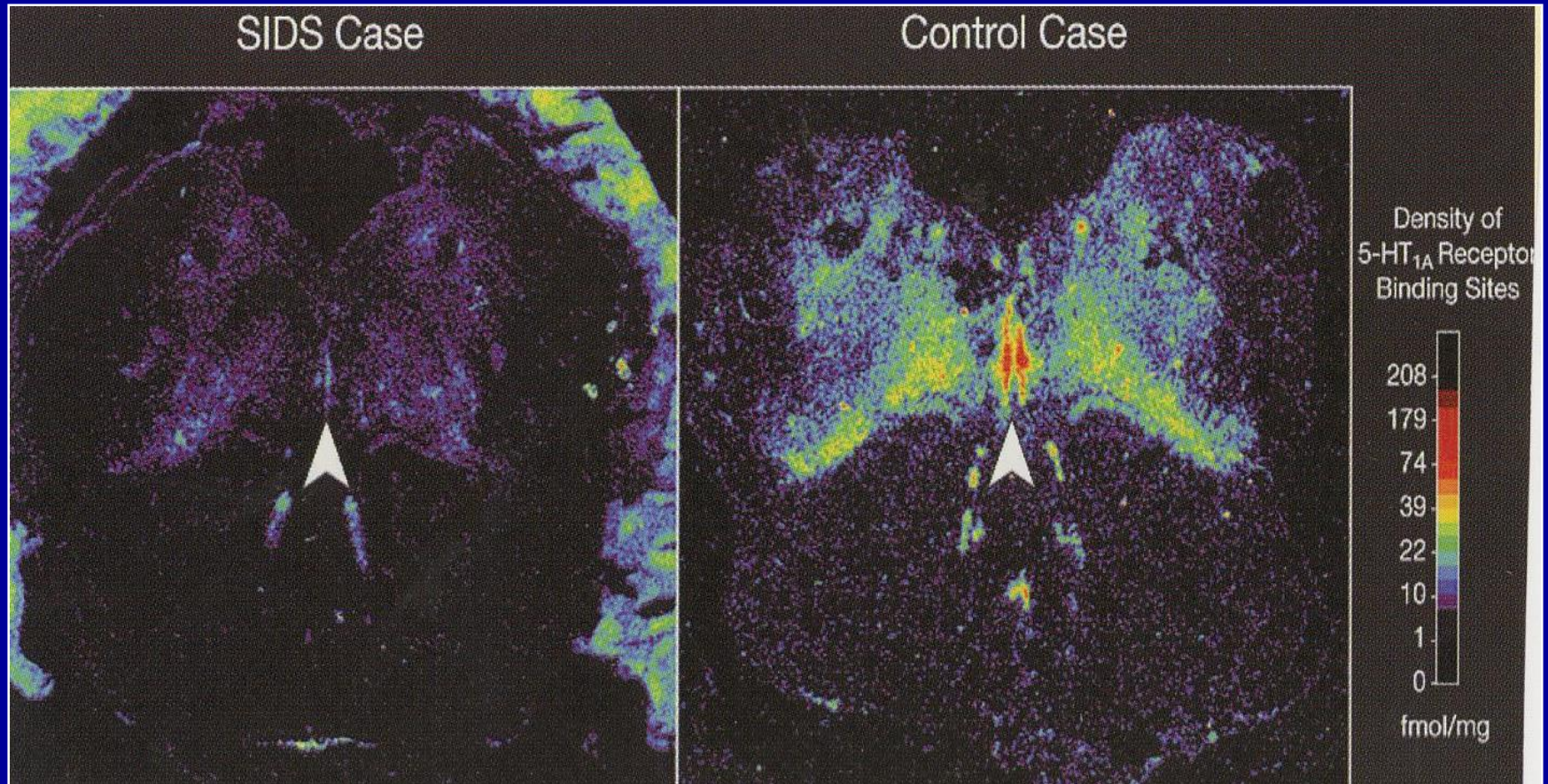
SIDS FACTS

- Higher incidence in preterm and low birth weight infants
- Associated with:
 - Young maternal age
 - Maternal smoking with pregnancy
 - Late or no prenatal care
- 2-3 times more common in African-American, American Indian, Alaska Native children

Triple Risk Model to Explain SIDS

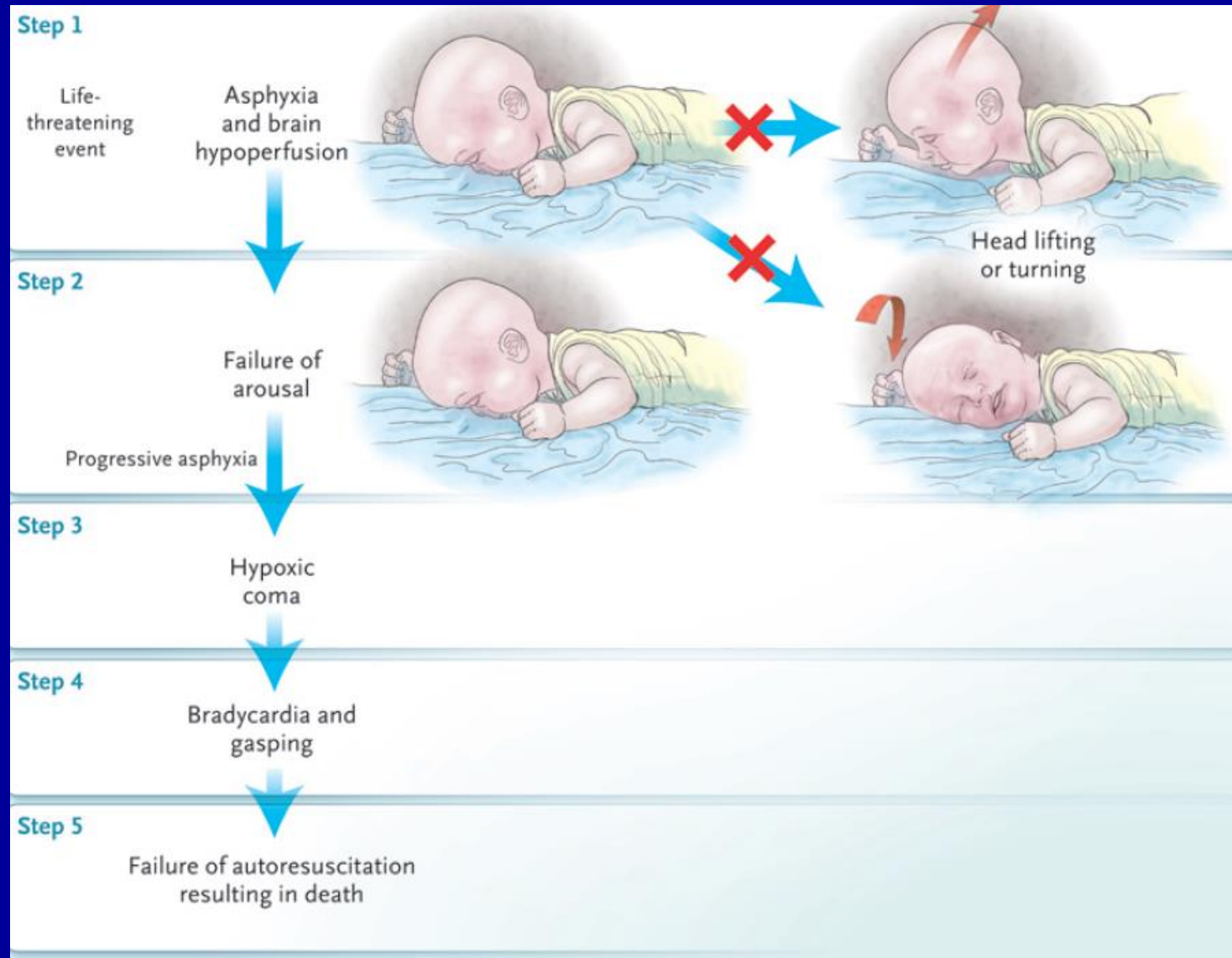


Paterson DS, Krous HF, Kinney HC, et al. JAMA. 2006



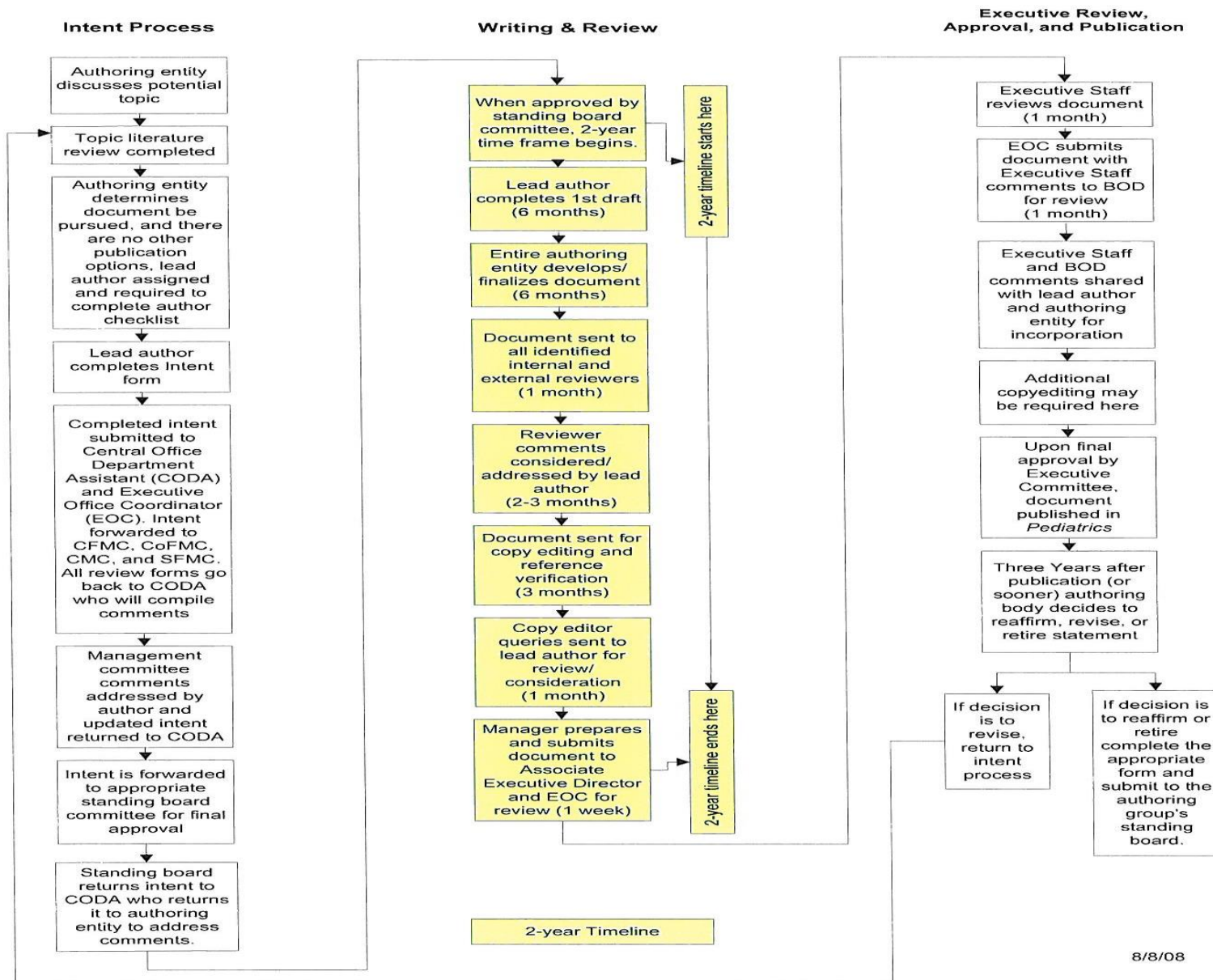
Serotonin receptor binding density lower in SIDS cases compared to controls.

An example of SIDS pathogenesis



Adapted from Kinney and Thach, 2009

Policy Development and Review Process Flow Sheet



Why do the recommendations change?

- Recommendations are not static
- 1992: AAP recommended side or back to reduce the risk of SIDS
- 2000: Back preferred, but side better than prone
- 2005: Back only

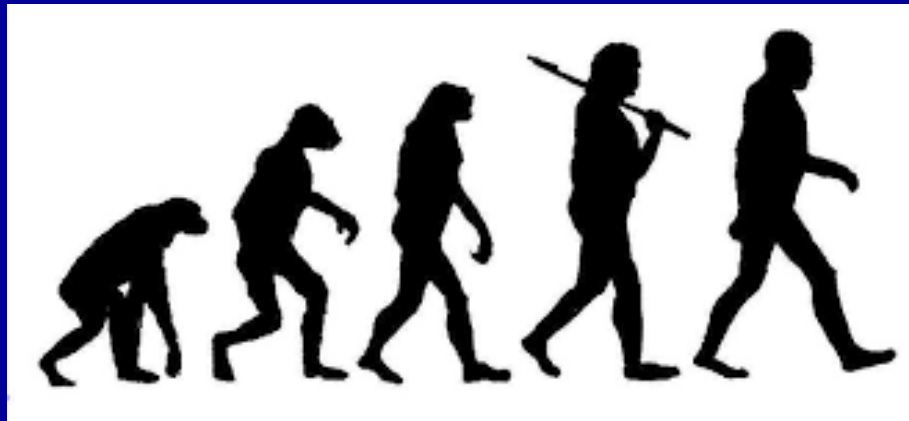


The recommendations change as the evidence evolves

- Statistics and risk factors may change
 - New risks emerge (e.g.: side positioning)
 - Different levels of risk?
- Policies and procedures may change
 - Better death scene investigations
 - Diagnostic shift
- Unintended consequences
 - Plagiocephaly, development
 - New tummy time recommendations

We are all learning and evolving TOGETHER!

- Feedback from “the field” is critical!
 - Unintended consequences
 - Wording of recommendations may be
 - Misinterpreted
 - No bedsharing = sofa sharing is ok
 - Translated poorly into other languages, cultures



Strength of Recommendation

- Scale based on the Strength of Recommendation Taxonomy (SORT)
 - A: There is good quality patient-oriented evidence
 - B: There is inconsistent or limited quality patient-oriented evidence
 - C: The recommendation is based on consensus, disease-oriented evidence, usual practice, expert opinion, or case series for studies of diagnosis, treatment, prevention or screening.



In General...

- Recommendations are to reduce the risk of SIDS and sleep-related suffocation, asphyxia, and entrapment
- Recommendations should be used consistently until 1 year of age
 - Most epidemiological studies upon which these recommendations are based include infants up to 1 year of age



2016 SIDS Task Force Policy Statement

Level A Recommendations:

- Back to sleep for every sleep
- Use a firm sleep surface
- Breastfeeding is recommended
- Room-sharing- infant on separate sleep surface
- Keep soft objects and loose bedding out of the crib
- Consider offering a pacifier at nap time and bedtime
- Avoid smoke exposure during pregnancy and after birth
- Avoid alcohol and illicit drug use during pregnancy and after birth

2016 SIDS Task Force Policy Statement

Level A Recommendations:

- Avoid overheating
- Pregnant women should receive regular prenatal care
- Do not use home cardiorespiratory monitors as a strategy for reducing the risk of SIDS
- Health care professionals, staff in newborn nurseries and NICUs, and child care providers should endorse the SIDS risk-reduction recommendations from birth
- Media and manufacturers should follow safe-sleep guidelines in their messaging and advertising

2016 SIDS Task Force Policy Statement

Level B Recommendations:

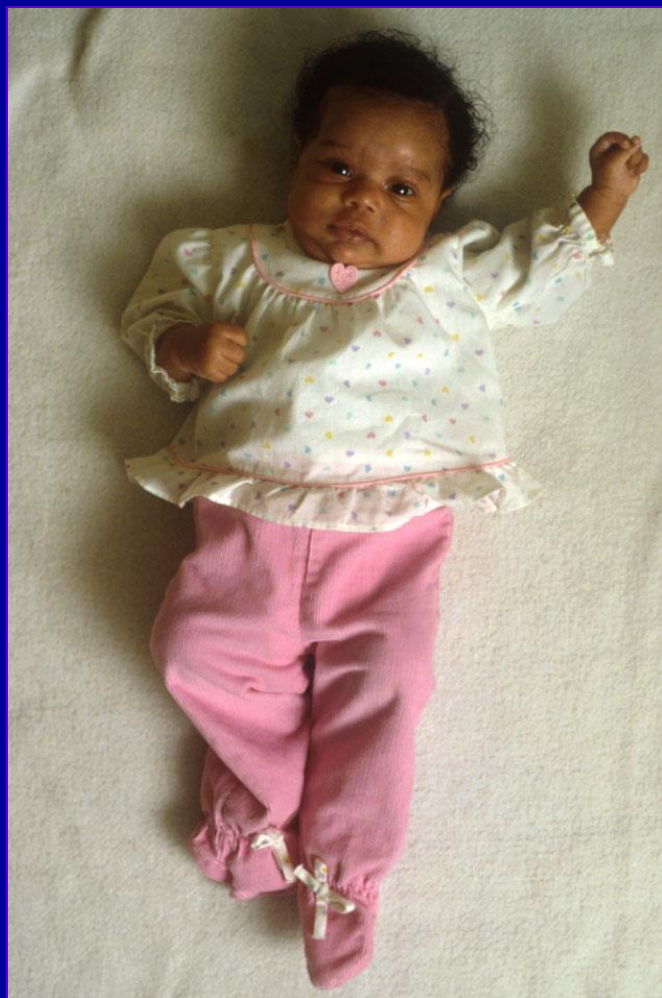
- Avoid commercial devices that are inconsistent with safe sleep recommendations
- Supervised, awake tummy time is recommended to facilitate development and to minimize development of positional plagiocephaly (flattening of skull)

2016 SIDS Task Force Policy Statement

Level C Recommendations:

- Continue research and surveillance on the risk factors, causes, and pathophysiological mechanisms of SIDS and other sleep-related infant deaths, with the ultimate goal of eliminating these deaths entirely
- There is no evidence to recommend swaddling as a strategy to reduce the risk of SIDS.

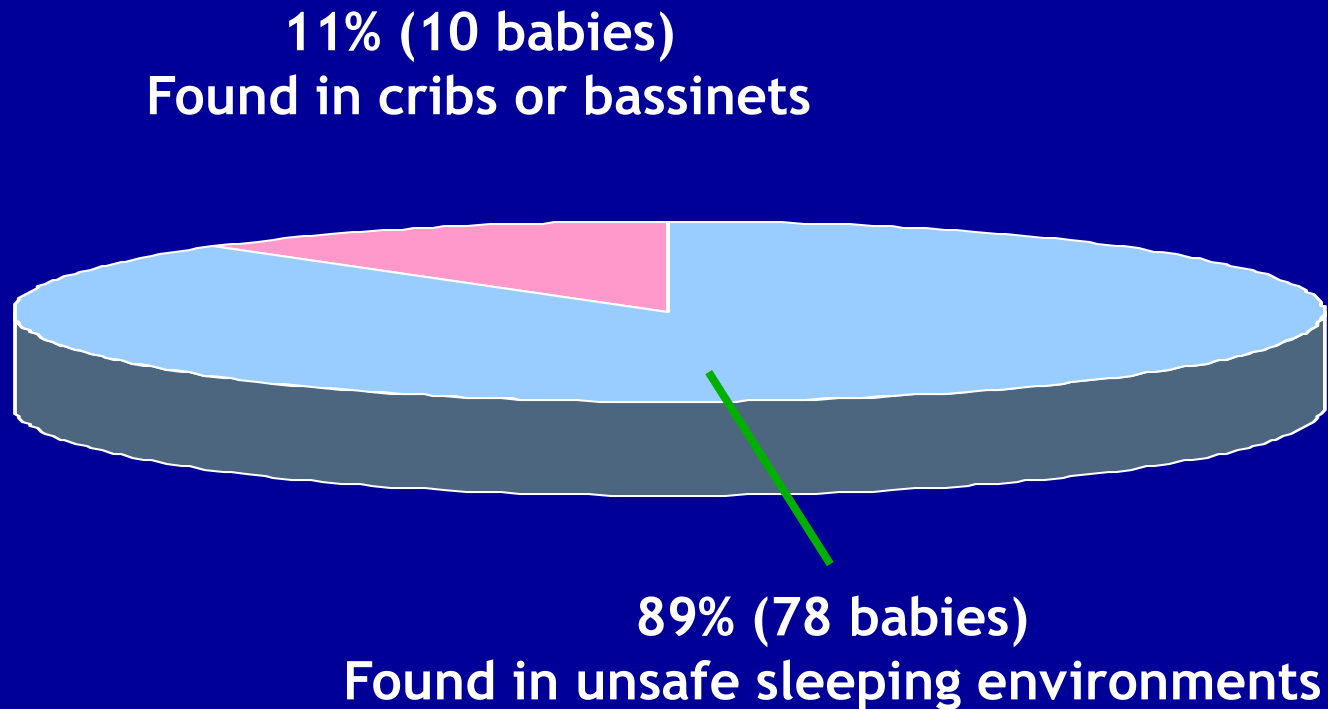
We Need to Move Beyond Back to Sleep



She's on her
back to sleep!



Allegheny County, Pa Study of 88 SIDS Deaths, 1994-2000



Correct Safe Sleep Environment



2016: What's New?



- The basics are the same!
- Some new evidence for specific areas
 - Skin-to-skin care for newborn infants
 - Use of bedside and in-bed sleepers
 - Sleeping on couches/armchairs and in sitting devices
 - Use of soft bedding after 4 months of age



And of course there's bedsharing

- Acknowledgment that parents may fall asleep while feeding baby
- Emphasize specific circumstances that greatly increase risk



Sleep Position for Healthy Newborns

- Skin-to-skin care is recommended for all mothers and newborns, regardless of feeding or delivery method, immediately following birth
 - Mom should be medically stable, awake, and able to respond to baby
- When mother needs to sleep or take care of other needs, infants should be placed supine in a bassinet.



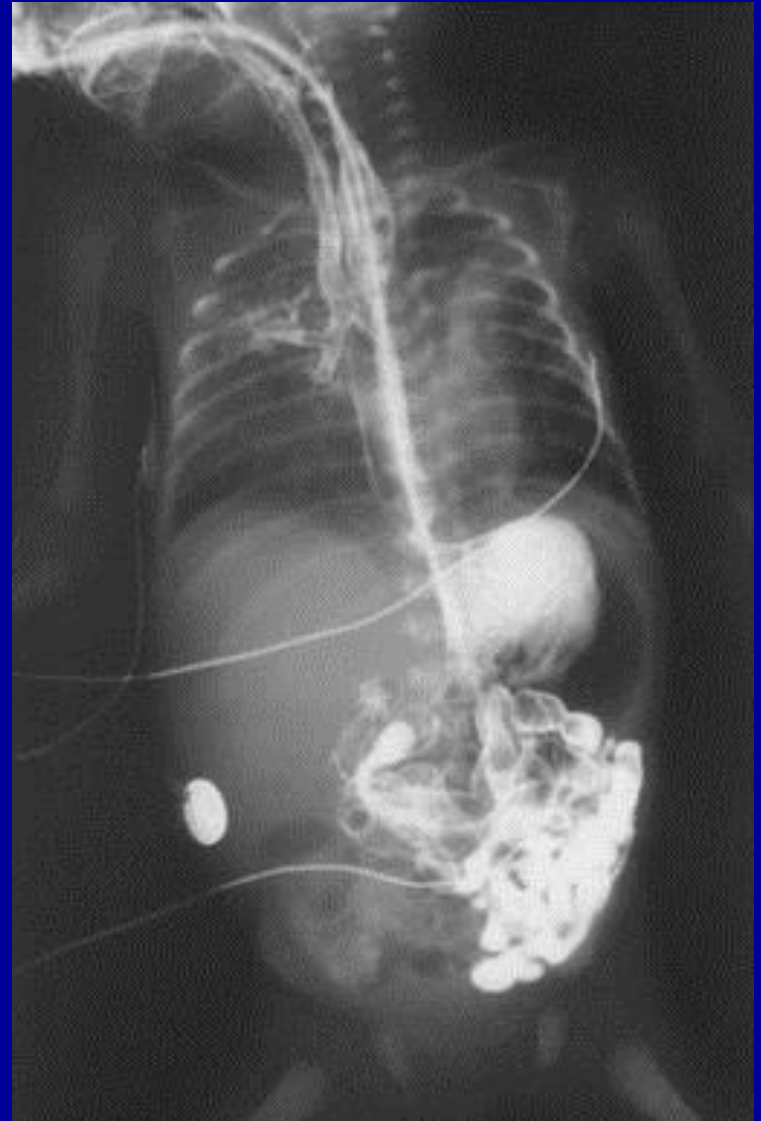
Sleep Position in Newborn Nursery

- Infants in the newborn nursery and infants who are rooming in with their parents should be placed in the supine position as soon as they are ready to be placed in the bassinet.
 - No evidence that placing infants on the side during the first few hours of life promotes clearance of amniotic fluid and decreases the risk of aspiration.



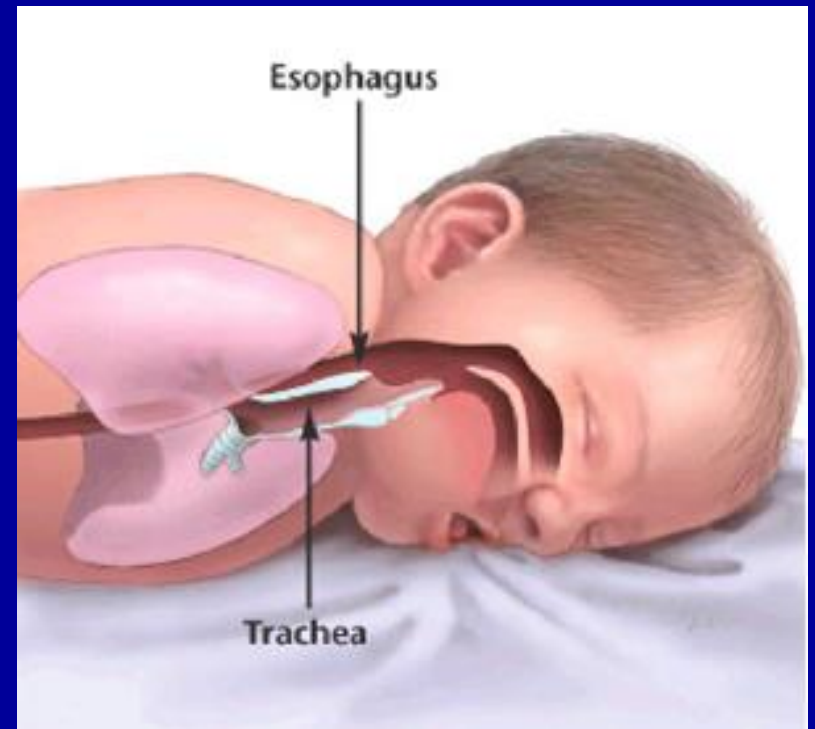
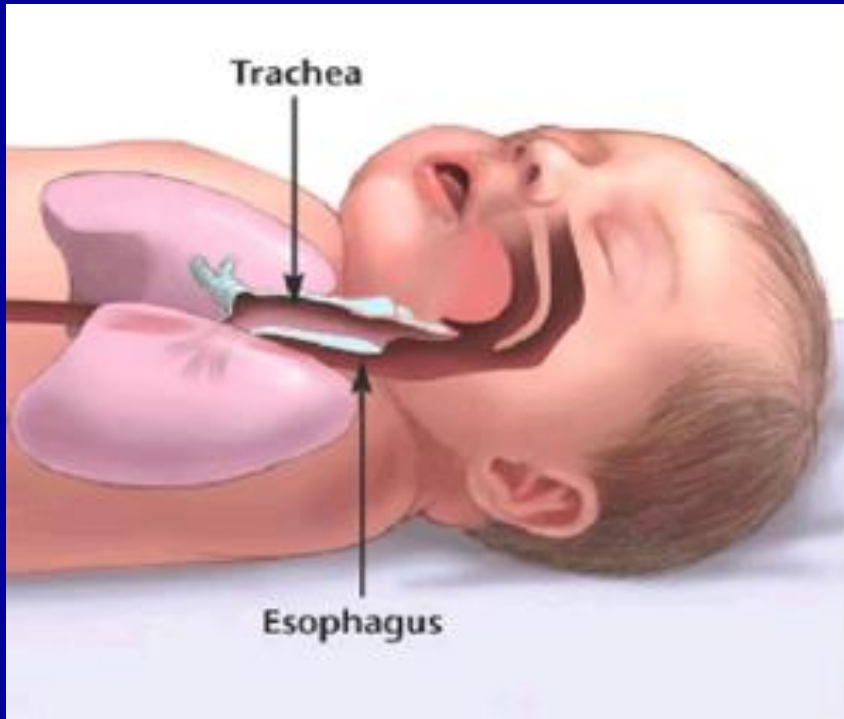
Sleep position and Reflux

- Infants with GE reflux should be kept supine
 - Unless the risk of death from complications of GE reflux is greater than the risk of SIDS
- Supine position does not increase the risk of choking and aspiration in infants with GE reflux
 - Protective airway mechanisms
- Do NOT elevate the head of the infant's crib
 - Ineffective in reducing GE reflux
 - Infant may slide to the foot of the crib - may compromise respiration.

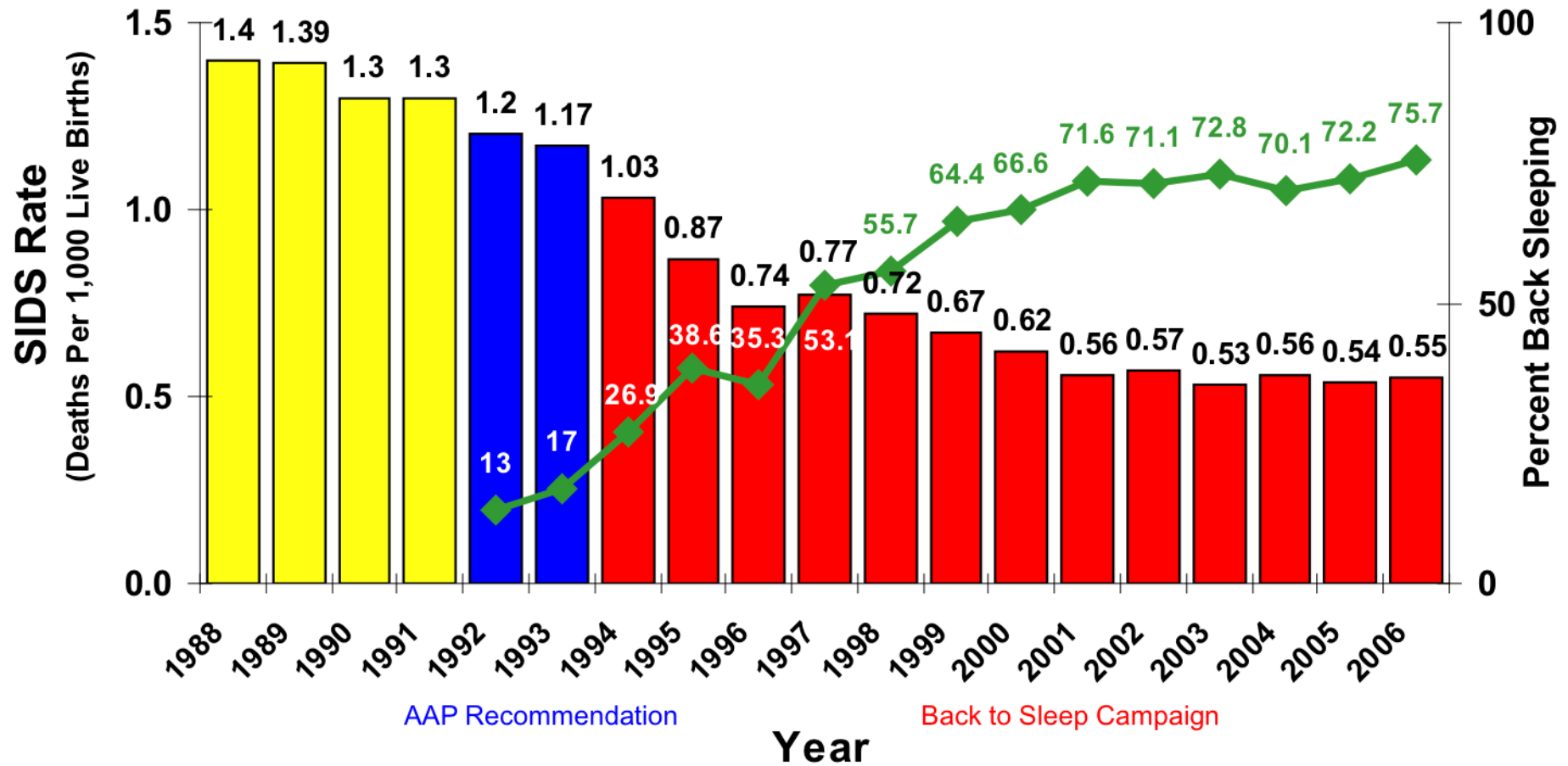


The Truth About Supine Sleep and Aspiration: Ending the Fallacy

Orientation of the Trachea to the Esophagus



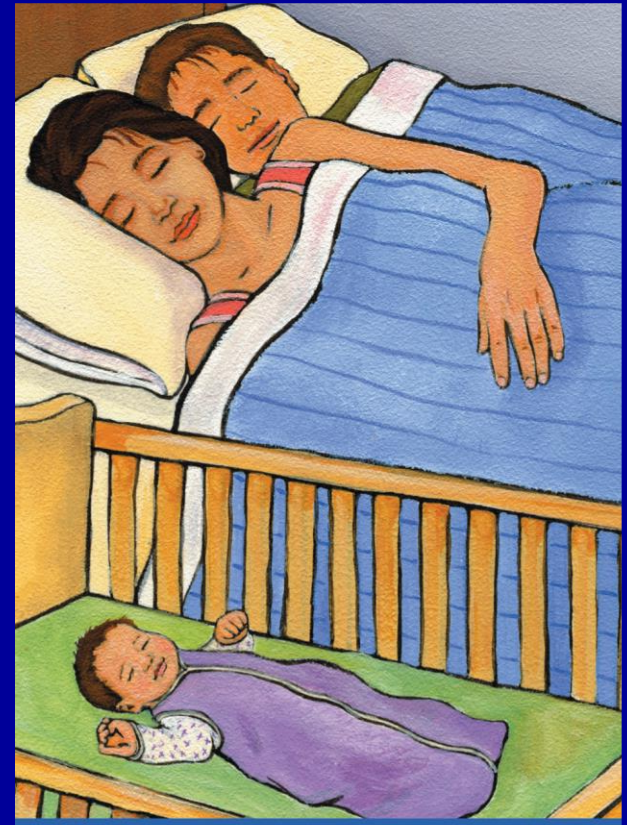
SIDS Rate and Back Sleeping (1988 – 2006)



SIDS Rate Source: CDC, National Center for Health Statistics,
Sleep Position Data: NICHD, National Infant Sleep Position Study.

Infant Sleep Location

- Infants should sleep in parents' room, close to parents' bed, but on a separate surface designed for infants
- Ideally for first year of life, but at least for the first 6 months



Room Share How Long? You're Kidding, Right?

- 2011: “all sleep recommendations are to be followed until 1 year of age”
- 2016: “roomsharing without bed-sharing... ideally for 1 year of age, but at least for the first 6 months”



Supporting Data

- 3 case-control studies comparing sleeping in a separate room vs. room sharing:
 - Tappin (Scotland): **AOR 3.26** (95% CI 1.03-10.35)
 - protection is significant for smoker mothers
 - Blair (England): **AOR 10.49** (95% CI 4.26-25.81)
 - protection is significant for both smoker and nonsmoker mothers
 - New Zealand Cot Death study: **AOR 2.85** (95% CI 2.04-3.85)

More Recent Data

- New Zealand SUDI study
 - 64% protection with roomsharing: **aOR 0.36**
(95% CI 0.19-0.71)
- Estimate of 50% reduction is very conservative
- None of the case-control studies stratify by age (months)

Why is Room Sharing Protective?

- SIDS- failure to arouse
- More small awakenings during the night
 - Stirrings, movement; not fully awake
- Postulation: protective effect from small awakenings
- Room sharing facilitates breastfeeding



Room Sharing and Sleep Quality

- Volkovich: room sharing vs. solitary sleep
 - RS mothers with more sleep disturbances
 - Infants with similar sleep quality
- Mao, Mindell: RS infants-more awakenings
- Montgomery-Downs, Doan: sleep quality in breastfeeding mothers \geq to formula feeding mothers
 - Exclusive breastfeeding = 30 min more sleep
- More study needed

Insight Study (Paul, 2017)

- Sleep questionnaire at 4, 9, 12, and 30 months
 - Sleep duration, overnight behaviors
 - Compared early vs late independent infants
- At 4 months:
 - Equal sleep duration
 - Early group had better sleep consolidation
 - Longest stretch 46 minutes

Insight Study (Paul, 2017)

- At 9 months
 - Longer sleep duration (40 min/night)
 - Better consolidation (100 min)
- At 30 months:
 - Longer sleep duration (45 min/night)
- Room sharing: 4 times more likely to transition to bed sharing overnight

Insight Commentary

(Hauck, Moon)

- Late RS: mean 7 hrs. longest sleep
- Is early consolidation desirable?
- Differences related to bedtime routines:
 - Early bedtime
 - number of night feeds
 - feeding back to sleep
- Focus on the routine, not early separation?

Feeding the Baby at Night

- Acknowledgment that parents may fall asleep while feeding baby
 - Safer to feed on bed than on sofa, couch, or armchair if you might fall asleep
 - No pillows, sheets, blankets, or other items that could obstruct infant breathing or cause overheating should be in bed
 - Return infant back to separate sleep surface as soon as parent awakens



Say NO to Couches, Sofas and Cushioned Armchairs!

- Never place baby for sleep on these surfaces
- Never sleep with a baby on these surfaces
- One of the **MOST** dangerous places for infant (OR 5.1-66.9)



High-Risk Bed Sharing Situations

- Age of < 4 months
- Preterm or LBW
- Smoked during pregnancy
- Bed sharer is current smoker (even if not smoking in bed)
- Bed sharer has used/is using meds or substances that could impair alertness or arousal
- Bed sharer is not parent (including other children)
- Soft surface (waterbed, couch, armchair)
- Soft bedding (pillows, quilts, comforters)



Bedsharing in Low-Risk Breastfed Infants

- Blair et al: AOR 1.6 (95% CI 0.96-2.7)
 - Age <14 weeks
 - Parents: No cigarettes or alcohol
 - Independent of feeding method
- Carpenter et al: AOR 5.1 (95% CI 2.3-11.4)
 - Age <3 months
 - Parents did not smoke
 - Mother: No alcohol or drugs
 - Breastfed infants



Independent Review

Dr. Robert Platt



- Very small numbers of low-risk babies
 - 24 in Blair's study
 - 12 in Carpenter's study
- Does not believe that data support definitive differences in 2 studies
- Some evidence of increased risk in this group, but cannot say how large the increased risk is
- Cannot conclude that bed sharing in this group is safe

Bed Sharing



Bed Sharing



Bed Sharing with Overlay



Bed Sharing with Overlay



Bed Sharing with Overlay



SIMULATED RECONSTRUCTION

Couch Sleeping



© Michigan Public Health Institute 2006

SIMULATED RECONSTRUCTION

Couch Sleeping



Couch Sleeping



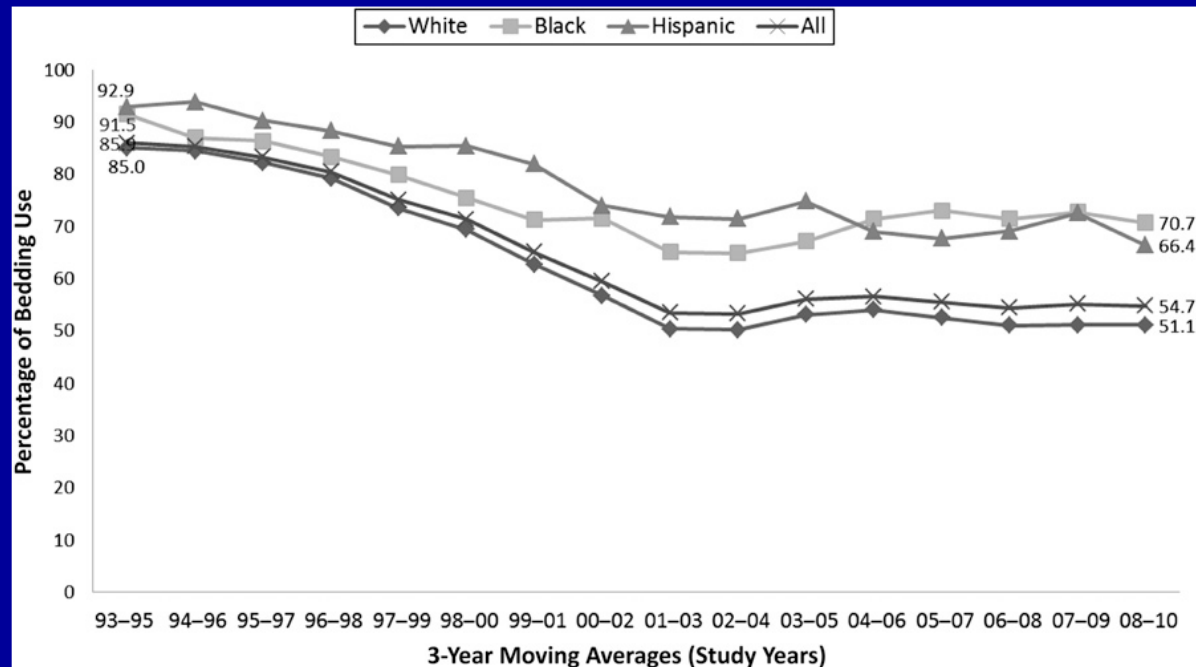
SIMULATED RECONSTRUCTION

Keep Soft Objects and Loose Bedding Out

- Risk of SIDS, suffocation, entrapment, strangulation
- Pillows, pillow-like toys, quilts, comforters, sheepskins, bumpers
- Loose bedding (blankets, sheets)
- Infant sleep clothing can be used instead



Unsafe Bedding: NISP Trends 1993-2102



- Decrease from 86% to 55%
- Rate of decline decreases 2001-10
- 83.5% for teen mothers
- Predictors of adjusted OR > 1.5
 - Young mothers
 - Non-white race, ethnicity
 - Less than college education

Why Use Soft Bedding?

- Comfort/Warmth
 - Extrapolation of own feelings
 - Misinterpret firm with taut
 - Soft + taut \neq firm
- Safety
 - Blankets, pillows, rolls to prevent falls



Soft Bedding for Older Infants

- Many parents recognize soft bedding is risk
- Increased complacency as baby gets older
- **Soft bedding is THE most important risk factor for infants 4-12 months old** (Colvin 2015)
- Infants roll into bedding and cannot extract themselves



To Swaddle or Not to Swaddle? That is the Question

- Pros:

- Calms the infant; promotes sleep; decreases number of awakenings
- Encourages use of the supine position

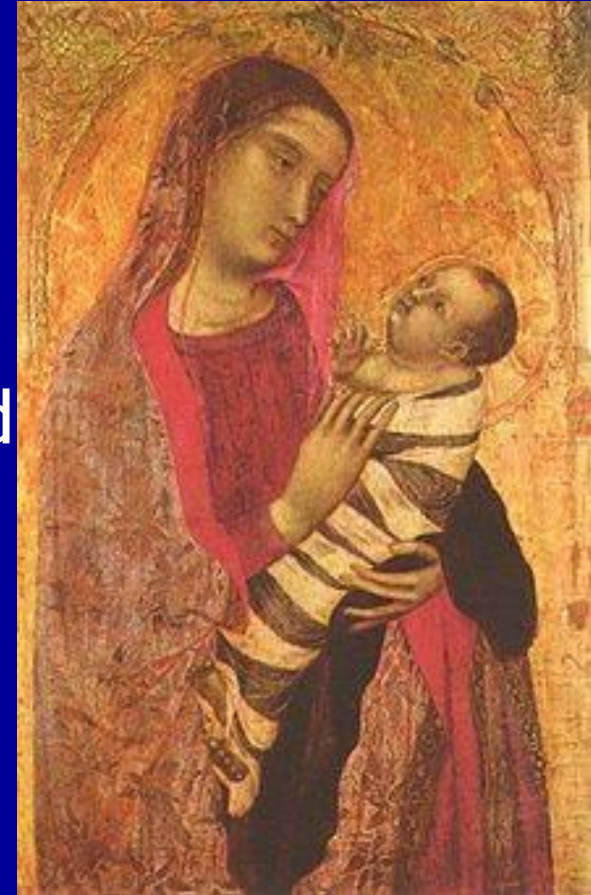


- Cons:

- Increased respiratory rate and reduced functional residual lung capacity
- Exacerbates hip dysplasia if the hips are kept in extension and adduction
- “Loose” swaddling becomes loose bedding
- Overheating, esp if the head is covered or the infant has infection
- Effects on arousability to an external stimulus remain unclear (conflicting data). There may be minimal effects of routine swaddling on arousal.

Swaddling

- There is insufficient evidence to recommend routine swaddling as a strategy to reduce the incidence of SIDS.
- Swaddling must be correctly applied to avoid the possible hazards
- Swaddling does not reduce the necessity to follow recommended safe sleep practices.



Swaddling- Is it Safe?

- McDonnell 2014, J Peds
 - Wearable blankets, swaddles: 10 deaths
 - 80% positional asphyxia, prone sleeping
 - 70% additional risk factors
 - Regular blankets, 12 deaths
 - 58% positional asphyxia, prone sleeping
 - 92% additional risk factors



Swaddling- More Questions...

- Pease 2016, Pediatrics
- Pooled OR = 1.38
 - Prone = 12.99
 - Side = 3.16
 - Supine = 1.93
- Increased risk with age
- Limitations:
 - Heterogeneity, definitions, other risk factors



www.healthychildren.org

- Swaddling (wrapping a light blanket snugly around a baby) may help calm a crying baby. If you swaddle your baby, be sure to place him on his back to sleep. Stop swaddling your baby when he starts to roll.



Pacifiers

- AAP recommendation: Consider offering a pacifier at nap time and bedtime.
- Studies consistently demonstrate a protective effect of pacifiers on SIDS
- Mechanism unknown:
 - Dislodge within 15 to 60 minutes
 - Decreased arousal threshold



Pacifiers and Breastfeeding

- Well-designed trials:
 - 2 found no association among term infants
 - 1 found no association among preterm infants
 - 1 found slightly decreased breastfeeding duration at one month if pacifier introduced in first week of life, but **NO difference if pacifier introduced after one month!**



Baby Friendly USA: Pacifiers

- Breastfeeding babies should not be given pacifiers by the staff of the facility, with the exception of:
 - Limited use to decrease pain during procedures when the baby cannot safely be held or breastfed (pacifiers used should be discarded after these procedures)
 - Babies who are being tube-fed in NICU
 - Other rare, specific medical reasons

Q. What if a mother requests that her infant be given a pacifier?

- After counseling and education, the mother's choice should be **respected**.
- The nurse should be knowledgeable regarding the AAP's policy and support the policy statement that pacifiers should not be used with breastfeeding infants until breastfeeding is well-established, after about 3-4 weeks.



Addressing Sleep Deprivation

- Give parents tools to cope with fussy babies
- Sleep-deprived parents may make poor judgments
- Make use of tools such as swaddling, side carrying, shushing, swinging, and sucking



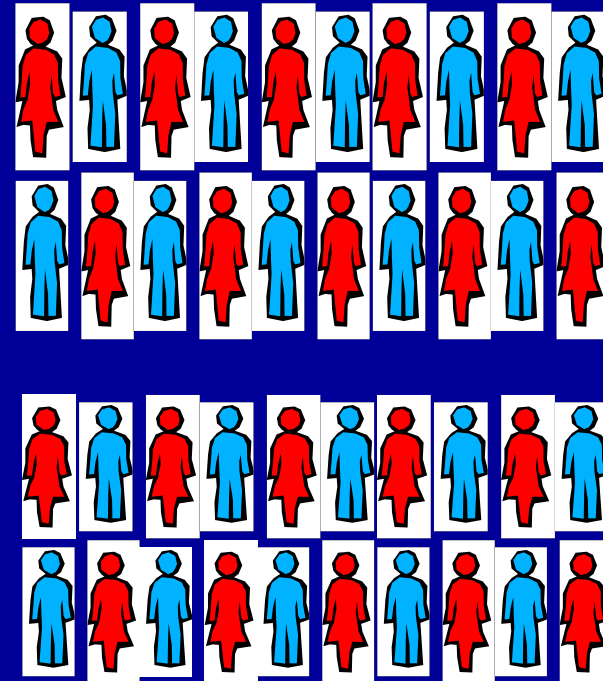
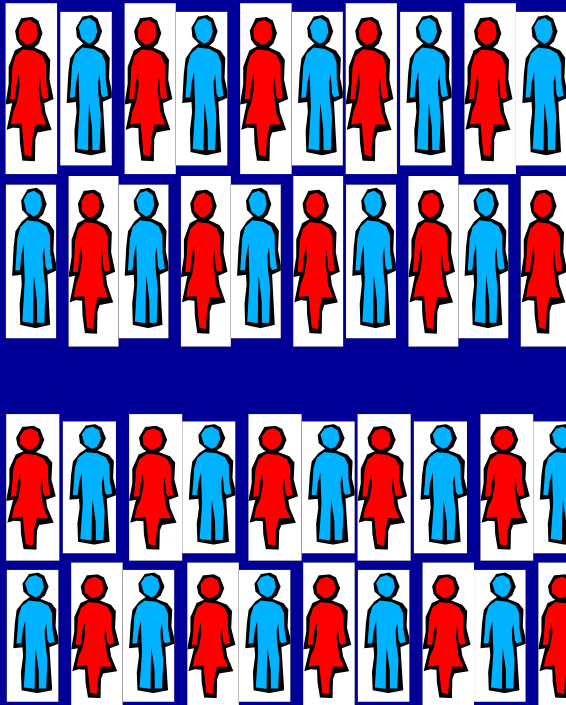
And finally...

- Health care providers should have open, frank, nonjudgmental conversations with families about their sleep practices



Impact of Eliminating Sleep-Related Deaths

78 children is equivalent to **4** kindergarten classrooms



Equanimity

- Balance SSC, Breast Feeding , and Safe Sleep is achievable!
- Focus: best health outcome for our babies!
- Requires: commitment, education, respect, and sensitivity



Namaste!!!



Contact Information

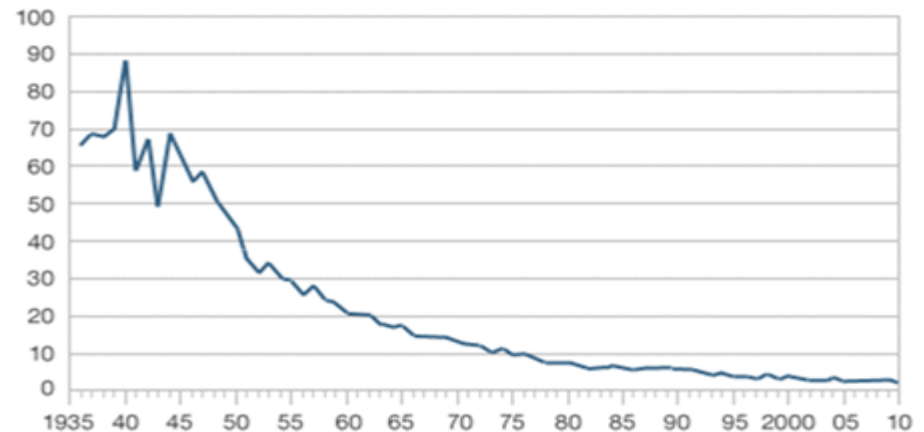
- mgoodstein@wellspan.org



Finnish Baby Box

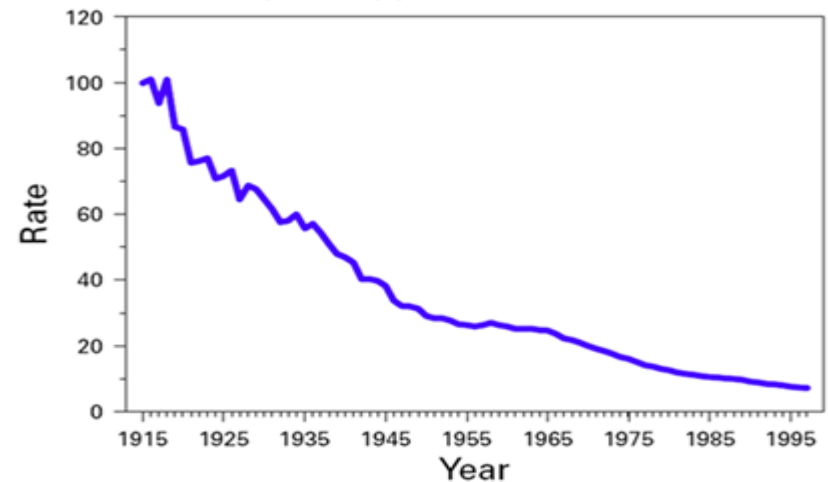
There are **NO STUDIES** to support the claim that the box reduces SIDS!

Infant mortality in Finland, 1936 to 2010 per 1,000 births



Source: Statistics Finland

FIGURE 1. Infant mortality rate,* by year — United States, 1915–1997



*Per 1000 live births.

Bedside and In-Bed Sleepers

Bedside Sleeper

- Attached to side of parental bed
 - CPSC safety standards available



In-Bed Sleeper

- Meant to be placed on parental bed
 - No CPSC safety standards available



Bedside and In-Bed Sleepers

- No published studies examining association between sleepers and SIDS or unintentional injury or death
- No recommendation for or against these products



Sleep Enablers: The Wahakura



- Woven flax bassinet for infants up to 5-6 months of age
- New Zealand
- Maori



Controversy: Should Bumper Pads be Used in Cribs?

Chicago Tribune

Breaking News, Since 1847

Council bans sale of crib bumper pads in Chicago

- Original intent of bumper pads: Prevent injury/death due to head entrapment
- Newer crib standards (slat spacing less than 2-3/8 inches) obviate the need for bumper pads!



Bumper Pad Fatalities

- Thach study using CPSC data found 3 mechanisms for deaths related to BPs:
 - Suffocation against soft “pillow-like” bumpers
 - Entrapment between mattress or crib and firm bumper pads
 - Strangulation from bumper pad ties



No Bumpers in the Crib!

- Thach: bumper pads only prevent minor injuries
- CPSC electronic survey system: potential benefit of preventing minor injuries far outweighed by risk of serious injury



Bumper Pad Deaths 2015

Scheers, N J Pediatrics

- 1985-2012: 48 deaths, 146 injuries
- 2006-2012: 23 deaths
- 29 more deaths in National CDR data base
- Total 77 cases



Avoid Commercial Devices Inconsistent with Safe Sleep Recommendations

- Be wary of devices that claim to reduce risk
- No harm in using “special” mattresses as long as they meet safety standards
- Still have to continue to follow safe sleep recommendations

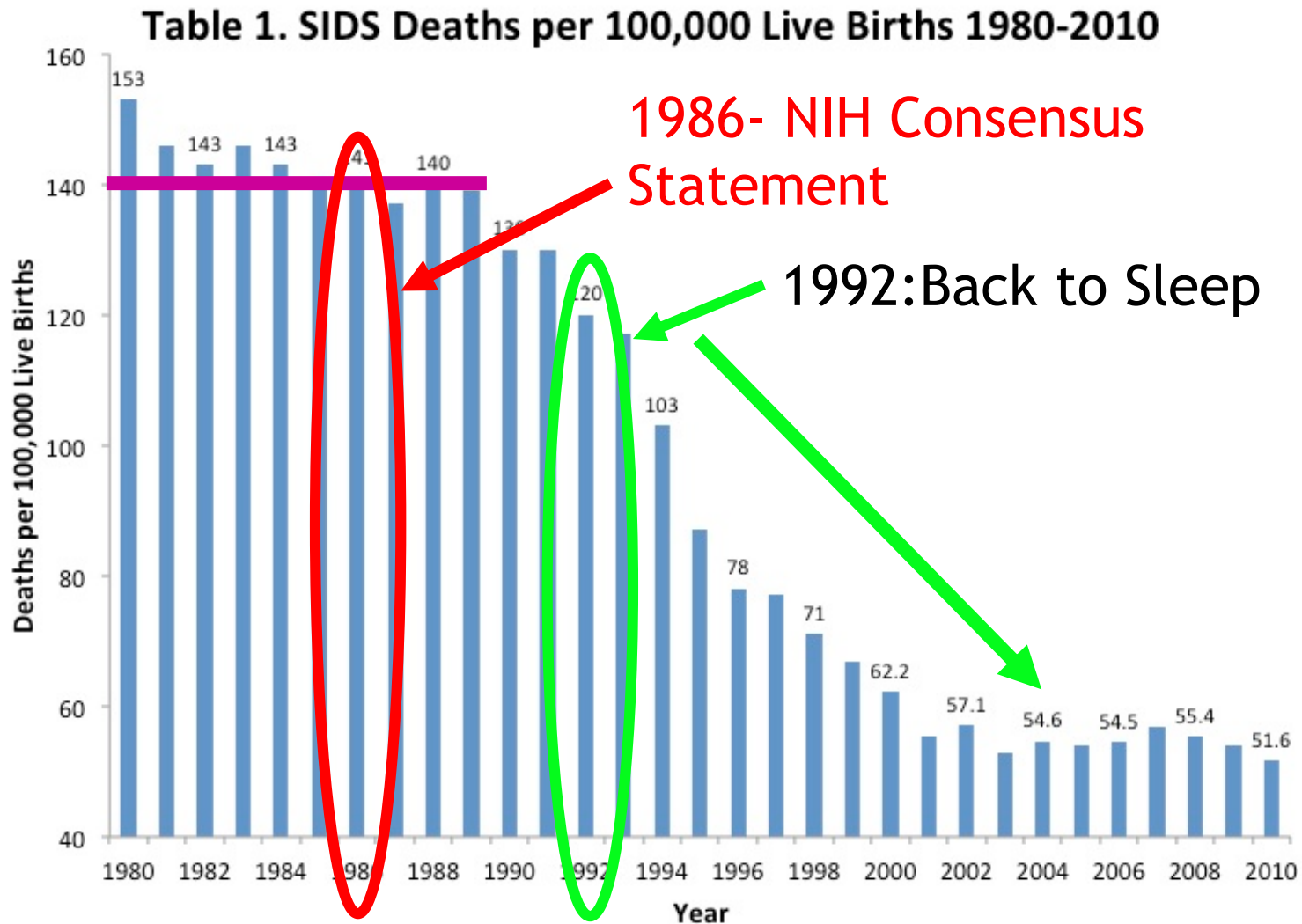


Home Apnea Monitors Do NOT Reduce SIDS Risk



- Monitors may be of value in selected infants (e.g., infants with apnea of prematurity)
- No evidence that routine in-hospital cardiorespiratory monitoring prior to discharge from the hospital can identify newborn infants at risk of SIDS

SIDS and Monitors: No Impact



New Products: Safe or Unsafe???



JPMA



- Junior Product Manufacturing Association
- Non-profit association: 250 manufacturers
- 95 percent of US prenatal to preschool products
- Certification Program is voluntary
- Built on ASTM standards
- When used properly, traditional bumper pads can help prevent limb entrapments and head injuries
- Displays marketed for use by children less than one year of age should not include items that present a suffocation or choking hazard to the infant, such as pillows...

ASTM



- American Society for Testing and Materials
- Develops voluntary consensus technical standards for materials, products
- Cribs: establishes performance requirements and test procedures to determine structural integrity
- Does not guarantee product performance

CPSC



- Consumer Product Safety Commission
- 500 employees oversee safety issues for thousands of product categories
- Studies ASTM standard's effectiveness and issues final consumer guidelines
- Voluntary over mandatory regulations
- Due process for all groups
- Issue Final Rules

CPSC

- Monitor Injuries: Recalls
- Reactive vs. Proactive
- Voluntary reporting (post-market testing)
- Drop rail cribs
- Side car standards
- New products:
 - Lack of data from SIDS studies

AAP



- American Academy of Pediatrics
- Task Force on SIDS
- Limited to available studies
- Studies will be severely limited for sorting out new product risk
 - Side car sleepers?
 - Finnish Baby Box?
- New products should be consistent with current guidelines
 - Extrapolation, judgment, common sense

Safer Bed/Bassinet Design



Position Matters

How to Safely Hold your Baby Skin-to-Skin

For Baby:

- Mouth and nose uncovered
- Place baby's face above the breasts
- Head turned to one side
- Neck straight not bent
- Make sure the face can be seen
- Keep blanket across baby's shoulders, away from the face
- Chest to chest with shoulders flat against Mom
- Dry hair & Covered Head
- Legs flexed

For Parents:

- Good support behind Mom's head, back and knees
- Mom should be sitting upright not lying back
- After breastfeeding, place baby back in upright position



Feeling Sleepy?

Place infant on back in bassinet for Safe Sleep

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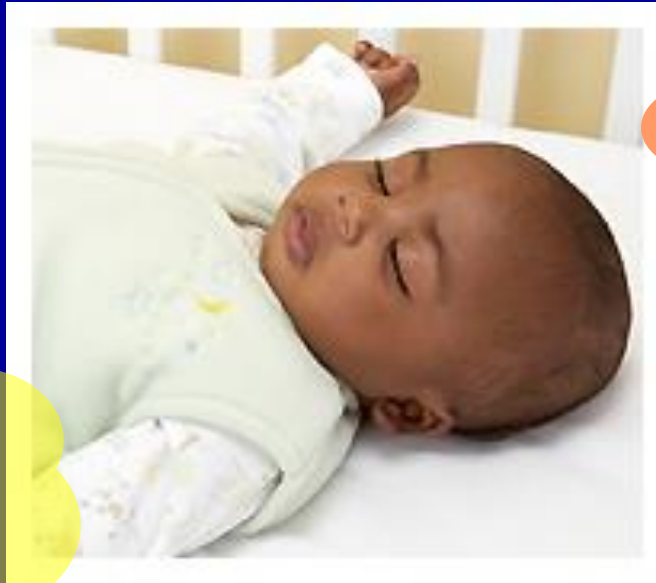


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Safe Sleep For Your Baby

**Put baby
on back**



**Avoid
overheating**

**Provide a
smoke free
environment**

**Consider
using a
pacifier**



**Use a firm
mattress with
No loose
bedding**

**Share your
room not your
bed with the
baby**